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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/676,046	09/30/2003	Michael P. Whitman	11443/158	7736

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EXAMINER	
LEUBECKER, JOHN P	
ART UNIT	**PAPER NUMBER**
3739	
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07/16/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/676,046	WHITMAN, MICHAEL P.	
	Examiner	Art Unit	
	John P. Leubecker	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 April 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6-8,10-34,36-58 and 60-82* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6-8,10-34,36-58 and 60-82* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 30, 2007 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 29-32, 36-58, 60-64 and 67-82 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilk et al. (WO 93/15648) in view of Hamlin et al. (Re. 36,434).

Wilk et al. disclose a shaft (14), an image capture device (CCD 90 or 152), a light source (26,34 or 160), a control module (12), and a power module (38) which can include a integrally housed power source (260, Fig.12). All components of Wilk et al. are "sterilizable" and "autoclavable" since everything is "sterilizable" and "autoclavable" (and the inherent size of the Wilk et al. device would allow for the device to fit inside any known machine for doing either). The shaft (14) is bendable using steering cables (72a,72b,74a,74b, Fig.2), and is thus flexible, and the steering cables are connected to motors (252,254,Fig.12). The light source and image capture device can be mounted at the distal end of the shaft (Figs.7 and 8) and the distal light

source can include a second power source (158, Fig.8) at the distal end of the shaft. The control module includes a video processor (not numbered but inherent in the circuitry associated with the CCD for supplying the video monitor (32), page 7, last paragraph) and a integrally mounted display screen (32). The shaft includes channels (52a,52b,52c) which are capable of conveying fluid or providing suction (60c,60a). Any of these channels can permit the passable of tools through the shaft. The shaft further includes a data transfer cable (88,Fig.4) for transmitting data to the video processor. The control module includes a control unit (any one of the housing for manually manipulating the device, the joystick (104, Fig.5), the buttons shown on the side of the display (Fig.5), or any of the controls of the suction source, air source, water source or light source) and a controller (any one of the electrical or mechanical means that control the suction source, air source, water source and light source, the processing circuitry which delivers an image to the display, motors (252,254), wireless transmitter (156,Fig.8), etc.). Since almost anything can be hand-held, the device of Wilk et al. is configured to be. The device of Wilk et al. is intended to be placed within the body so, as best understood, it is configured as an endoscope, proctoscope and anoscope.

As for the shaft being sealed, Wilk et al. teaches that the channel that receives the optical guide member is "closed at the distal end" (page 5, fourth full paragraph) (note window 28 in Figure 3 for example) and that the "present endoscope is easier to clean and maintain in a sterile condition" (page 5, fifth full paragraph). This suggests to the reasonable person that window seals the shaft, otherwise the optical guide member (20) would not remain in a sterile condition. Since the claimed subject matter sets forth the condition for being sterilized as being "sealed", at least the sealed shaft will meet this limitation. It is noted that the optical guide member (20)

would also appear to be sealed at least at the distal end, and thus, as per the newly added subject matter, sterilizable. There is no reason to believe that any portion of the Wilk et al. device could not be sterilized or autoclaved, even though that might not be intended.

Clearly, regarding the citations in Wilk et al. from the paragraph immediately above, the sterility must also depend not only on the sealed window, but the shaft (tube 14) itself (a window sealed with the shaft would have no more effect that one that is not, if the shaft itself is not sealed). Keeping the optical guide member in a sterile condition (while the device is inside of a body) would inherently require the material making up the outside of the tube to be "fluid-tight", if not "air-tight".

Although it would appear to be inherent that the proximal end (coupling element 50) of tube (14) is connected to control module (12) in a sealed manner to maintain the sterile condition of the elements on the interior, as pointed out above, Wilk et al. fails to explicitly state this. Hamlin et al. teach in the relevant field of endeavor to place a sealed, sterilizable or discardable tube (18) over an optical guide member (12) such that the connection of the tube to the control module (10) is sealed (note Figs.3, 4 and 7, and col. 6, lines 1-9). This prevents contamination from entering the interior of tube (18) and thus contamination of the optical guide member (12) (col.6, lines 4-9). It would have been obvious to one of ordinary skill in the art, if not already inherent, to have similarly sealed the proximal end of the tube (14) of Wilk et al. when connected to the control module (12) to prevent contamination from entering the interior of the tube. This is consistent with the teaching of Wilk et al. to maintain the optical guide member in a sterile condition. Such modification thus providing an interior of the shaft having a fluid tight seal from the environment at the distal (as previously pointed out) and proximal ends.

4. Claims 1-4, 6-8, 10-28, 33, 34, 65 and 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilk et al. in view of Hamlin et al., as set forth above and further in view Kanno et al. (U.S. Pat. 4,884,133).

Wilk et al. in view of Hamlin et al. disclose the elements as set forth above including a light source but fails to specify the nature of the light source. Kanno et al. demonstrates that is known to use an LED or an array of LEDs in an endoscope for providing illumination light (note 26G, 26R, 26B of Figure 1(c) for example). Since it is well known and well within the ordinary skill in the art to recognize the advantages of LEDs (e.g., low power requirements, small size, etc.) over normal incandescent lamps and use of LEDs in an endoscope for the same purpose Wilk et al. (i.e., illumination) has been previously contemplated, it would have been obvious to one of ordinary skill in the art at the time of the invention to have used LEDs for the generic "light source" of Wilk et al.

Response to Arguments

5. Applicant's arguments filed April 30, 2007 have been fully considered but they are not persuasive.

Most arguments are directed to the newly added limitation regarding the interior of the shaft being sealed from the environment. The rejections above address such limitation.

Applicant also argues that teachings of Wilk et al. (i.e., "there is no need to subject optical guide member 20 to sterilizing and cleaning operations which may damage the optical guide and eventually wear it down") "evidences that an interior of the optical guide member 20

is not sealed from the environment at its proximal and distal ends so as to be sterilizable for reuse". The Examiner respectfully disagrees since such statement more accurately implies that the optical guide member 20 may be damaged after repeated sterilizations (i.e., "eventually wear it down). This is known in the art as evidenced by Hamlin et al. (Re. 36,434) at col.1, lines 56-60. The Examiner submits that the optical guide member can not "eventually" be worn down and damaged by repeated sterilizations if it were not sterilizable to being with.

In any event, the claims define being "sterilizable" structurally as having an interior having a fluid tight seal from the environment at the distal end and the proximal end, which limitations have been addressed with respect to the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John P. Leubecker whose telephone number is (571) 272-4769. The examiner can normally be reached on Monday through Friday, 6:00 AM to 2:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/jpl/

John P. Leubecker
Primary Examiner
Art Unit 3739

jpl